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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,577	05/26/2005	Andreas Bergmann	2582.0009	2150

23405 7590 09/17/2007

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EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
09/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,577	BERGMANN ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 have been canceled.

Claim 13 is pending and currently under examination as they read on a method of for the detecting thyroid stimulating hormone (TSH) receptor autoantibodies in a biological sample.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, PCT/EP03/12129, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claim 13 is <u>not</u> supported by the disclosure of the above priority applications in the recitations of "exogenous".

Therefore, the priority date for claim 13 is deemed to be the national stage entering date under 35 U.S.C. 371, i.e. **05/26/2005**.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

Information Disclosure Statement

3. Applicant's IDS filed 07/21/2006 is acknowledged and has been considered.

Specification

4. Applicant is requested to review the application for any spelling error, use of trademarks, embedded hyperlinks and/or other form of browser-executable code (e.g., see page 8).

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Applicant is requested to identify the written support for claim 13 particularly the claimed limitations of "exogenous". The only support for "exogenous" is noted in the preliminary amendment, filed 05/26/2005.

Applicant is invited to amend the specification to provide antecedent basis for the claimed subject matter.

Alternatively, Applicant is invited to identify the written support for instant claims in the specification as filed.

Claim Objections

6. Claim 13 is objected to because of the following informalities:

The abbreviation, "TSH", should be spelled out first time appearing in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "exogenous" in claim 13 is a relative term which renders the claim indefinite. The dictionary definition for "exogenous" is "*derived or developed from external cause*" (see Webster's II, New Riverside University Dictionary, 1984, Houghton Miffin Company, Boston, MA, USA, page 453, left column, 14th entry). The term "exogenous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree (i.e., the external source of the antibody), and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is reminded that amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Morgenthaler et al. (*Mol. And Cell. Endo.* 2003, 212:73-79, see entire document).

Morgenthaler et al. teach a method for the detection of TSH receptor autoantibodies in a biological sample comprising: a) contacting said biological sample with TSH receptor that is immobilized on a solid support in the presence of exogenous labeled TSH receptor autoantibodies for a time sufficient for the autoantibodies in the biological sample to competitively bind to the TSH receptor; b) removing unbound labeled TSH receptor autoantibodies; and c) detecting TSH receptor autoantibodies in the biological sample by measuring the amount of label bound to the TSH receptor (e.g., see Materials and methods and Results, pages 74-76).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

11. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Parmentier et al. (U.S. Patent 6,228,597 B1, see entire document) and that a wash step to remove unbound antibodies is inherent to a competitive binding assay as evidenced by Weir et al. (*Handbook of Experimental Immunolgoy in Four Volumns*, Volumn 1: Immunochemistry, Forth Edition, 1986, Blackwell Scientific Publications, Palo Alto, CA, USA, pages 34.7-34.8, see entire document).

Parmentier et al. teach a method for the detection of TSH receptor autoantibodies in a biological sample comprising contacting said biological sample with TSH receptor that is immobilized on a solid support in the presence of labeled TSH receptor antibodies for the autoantibodies in the biological sample to competitively bind to the TSH receptor and detecting TSH receptor autoantibodies in the biological sample by measuring the amount of label bound to the TSH receptor (e.g., see column 8, lines 59-68; column 9, lines 1-22; and claims 9-10).

Although Parmentier et al. is silent on using exogenous labeled TSH receptor autoantibodies, given the specification does not provide a definition for "exogenous", and the definition disclosed in the specification for TSH receptor autoantibodies does not limit the autoantibodies to affinity-purified polyclonal autoantibodies from human (see pages 9 and 13 of specification), under the broadest reasonable interpretation, the labeled anti-TSH receptor polyclonal antibody meets the limitation of the present claim.

Moreover, Parmentier et al. is silent on the step of removing unbound labeled TSH receptor autoantibodies. However, an ordinary artisan would have immediately envisaged that in a competitive binding assay, a wash step to remove unbound antibody is an inherent step in the assay as evidenced by Weir et al. (see page 34.8, right column, Procedure, step 4).

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parmentier et al. (U.S. Patent 6,228,597 B1) in view of Brown et al. (*J. of Clinical Endocrinology and Metabolism*, 1983, 56:156-163, cited in IDS).

The Parmentier reference was been discussed supra.

Although the specification does not provide a definition for "exogenous", for examination purposes, "exogenous" will read on affinity-purified polyclonal autoantibodies against TSH receptor.

Parmentier et al. teach using labeled polyclonal antibody against TSH receptor for the competitive binding assay (see entire document). Parmentier et al. do not explicitly teach that the labeled antibody is an affinity-purified human polyclonal autoantibody.

However, it is well known in the art at the time of filing to affinity-purify polyclonal autoantibodies against TSH receptor from human serum as demonstrated by Brown et al. (see entire document, in particular page 157, *Membrane purification*).

In particular, Brown et al. teach using the affinity-purified human polyclonal autoantibodies against TSH receptor in a competitive binding assay in which the affinity-purified human polyclonal autoantibodies compete with labeled bovine TSH to bind TSH receptor on a solid support (see page 158, *Assay for TBII*).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of filing, to label the affinity-purified human polyclonal autoantibodies against TSH receptor that was taught by Brown et al. in a competitive binding assay for detecting anti-TSH receptor autoantibodies in a biological sample as taught by the Parmentier reference.

In addition, one of ordinary skill in the art would have been motivated to use labeled affinity-purified human autoantibodies against TSH receptor given the teaching by Parmentier in that the labeled polyclonal antibody against TSH receptor is preferably in a purified form from animal origin (see column 8, lines 59-62).

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 13 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,228,597. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reason:

The instant claim and claim 9 of U.S. Patent No. 6,228,597 are drawn to the same or nearly the same and obvious methods for the detection of TSH receptor autoantibodies in a biological sample with the same or nearly the same and obvious labeled anti-TSH receptor antibody competing with the anti-TSH receptor autoantibodies in the biological sample for binding of TSH receptor to accomplish the same or nearly the same and obvious endpoint in detecting anti-TSH receptor autoantibodies in the biological sample.

Therefore the instant and patented claims anticipate or render obvious one another.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
September 13, 2007

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9/13/07